



EUROPE

THE ARTS
CHILD POLICY
CIVIL JUSTICE
EDUCATION
ENERGY AND ENVIRONMENT
HEALTH AND HEALTH CARE
INTERNATIONAL AFFAIRS
NATIONAL SECURITY
POPULATION AND AGING
PUBLIC SAFETY
SCIENCE AND TECHNOLOGY
SUBSTANCE ABUSE
TERRORISM AND
HOMELAND SECURITY
TRANSPORTATION AND
INFRASTRUCTURE
WORKFORCE AND WORKPLACE

This PDF document was made available from www.rand.org as a public service of the RAND Corporation.

[Jump down to document](#) ▼

The RAND Corporation is a nonprofit research organization providing objective analysis and effective solutions that address the challenges facing the public and private sectors around the world.

Support RAND

[Browse Books & Publications](#)

[Make a charitable contribution](#)

For More Information

Visit RAND at www.rand.org

Explore [RAND Europe](#)

View [document details](#)

Limited Electronic Distribution Rights

This document and trademark(s) contained herein are protected by law as indicated in a notice appearing later in this work. This electronic representation of RAND intellectual property is provided for non-commercial use only. Unauthorized posting of RAND PDFs to a non-RAND Web site is prohibited. RAND PDFs are protected under copyright law. Permission is required from RAND to reproduce, or reuse in another form, any of our research documents for commercial use. For information on reprint and linking permissions, please see [RAND Permissions](#).

This product is part of the RAND Corporation technical report series. Reports may include research findings on a specific topic that is limited in scope; present discussions of the methodology employed in research; provide literature reviews, survey instruments, modeling exercises, guidelines for practitioners and research professionals, and supporting documentation; or deliver preliminary findings. All RAND reports undergo rigorous peer review to ensure that they meet high standards for research quality and objectivity.

TECHNICAL REPORT

Improving Patient Safety in the EU

Assessing the expected effects of
three policy areas for future action

Annalijn Conklin, Anna-Marie Vilamovska,
Han de Vries, Evi Hatziandreu

Prepared for the European Commission

The research described in this report was prepared for the European Commission. The opinions expressed in this study are those of the authors and do not necessarily reflect the views of the European Commission.

The RAND Corporation is a nonprofit research organization providing objective analysis and effective solutions that address the challenges facing the public and private sectors around the world. RAND's publications do not necessarily reflect the opinions of its research clients and sponsors.

RAND® is a registered trademark.

© Copyright 2008 European Commission

Published 2008 by the RAND Corporation
1776 Main Street, P.O. Box 2138, Santa Monica, CA 90407-2138
1200 South Hayes Street, Arlington, VA 22202-5050
4570 Fifth Avenue, Suite 600, Pittsburgh, PA 15213-2665
Westbrook Centre, Milton Road, Cambridge CB4 1YG, United Kingdom
RAND URL: <http://www.rand.org>
RAND Europe URL: <http://www.rand.org/randeurope>
To order RAND documents or to obtain additional information, contact
Distribution Services: Telephone: (310) 451-7002;
Fax: (310) 451-6915; Email: order@rand.org

Executive Summary

This study assesses the extent of the current problem of poor patient safety in Europe as well as the expected impacts of proposed policy areas for future mitigating action

There is converging evidence that patient safety incidents such as medical errors and adverse events in delivering healthcare are far more widespread and more harmful to patients than was previously realised, or acknowledged. In fact, it is now indisputable that patient safety is a “**most important common issue in healthcare internationally**”. The aim of this study is to support the Commission’s Impact assessment on the Patient Safety initiative by establishing the scope of the problem in Europe and also assessing the potential impacts of three policy areas for action.

In defining the problem of patient safety in Europe, we know that adverse events and near misses exist at high rates at a systemic and an individual level in healthcare systems in Europe as well as globally. The existing body of literature, increasingly with European contributions, reinforces the now well-known fact that patient safety is (1) a grave public health problem with significant and even deadly health consequences for affected patients, and their families; and (2) a high economic burden on limited health resources.

We also know that there are efforts being made in many countries in Europe and elsewhere to implement mitigating strategies to improve patient safety, such as national reporting and learning systems (RLS). However, we found that most of these are yet to be evaluated for their social and economic impacts on key stakeholder groups. Hence, our report provides an initial attempt to offer such evidence based on key informant interviews with experts on Patient Safety in Europe. We support our qualitative findings by discussing at the end of the report the growing body of literature on the positive impact of interventions like RFID (radio frequency identification) in healthcare, in terms of a demonstrated better quality of care including better patient safety.

DG SANCO identified three policy areas for future action to improve patient safety in Europe

The European Commission for Health and Consumer Protection wishes to improve patient safety in Europe and has proposed three policy areas for future action on this important issue. The policy areas for action (henceforth referred to as action areas)

considered include the following: (1) the establishment of “an effective reporting and learning mechanisms” (Action Area 1); (2) the establishment of “redress mechanisms” for fair compensation to injured patients (Action Area 2); and, (3) the “development and use of knowledge and evidence” (Action Area 3).

A variety of methods were used to assess possible impacts of the proposed policy areas for future action

This report reviews both the European and international literature; examines the scope of the problem as it applies to the EU-27; and assesses the potential health benefits that could be realised under the assumption that comprehensive patient safety actions will materialise and will also improve patient health outcomes. We employed both qualitative and quantitative methodologies. First, we conducted semi-structured in-depth interviews with members of the High Level Working Group on Patient Safety to complement the rather sparse relevant epidemiological data at the EU level. Second, we performed a grouping exercise to facilitate our understanding of the interview results and to obtain some overview measure of how countries can be classified in terms of their patient safety activities. The purpose of our development of a taxonomy (classification) was twofold: (1) to reveal the clustering of patient safety actions around certain characteristics that became apparent from our data (literature and interviews), and (2) to create a meaningful frame of reference for the subsequent quantitative analysis. Third, we extrapolated country-specific estimates on adverse events and their consequences, as reported in the literature, to the entire EU-27. Fourth and finally, we constructed scenarios to estimate the potential health benefits (i.e. safety events, deaths and disability avoided, and additional hospital days prevented) that could be expected if improvements in the proposed policy areas were made by the EU member states.

There is strong potential for great return on investment in improving patient safety, but the evidence base is under-developed

There was strong consensus among experts that action areas to improve patient safety have a strong potential for a great return on investment. In particular, the economic impact of effective reporting and learning systems was believed to be moderate to quite large in the short term but will save money in the long term from avoided costs of adverse events. The economic impact of redress mechanisms were unclear as they will depend on the type of mechanism in place and the threshold of severity established by a particular member state. Similarly, experts contested whether the economic impact of developing and using knowledge and evidence at the EU level will be positive or negative, and by how much.

The evidence base for the expected economic impacts of the three proposed policy areas is under-developed in Europe. Our interview respondents consistently noted the fact that no one in Europe has conducted a health economics (cost-effectiveness) study of any of the three proposed action areas for policy to improve patient safety. Our own review of the literature supports this expert consensus, as such evidence appears only to be available from international sources. It is clear that an empirical assessment of the economic impacts of

the proposed policy areas for future action, demonstrating the strong potential for a great return on investment, will require a longitudinal, cross-national study for future comparisons and learning.

Many stakeholders will benefit substantially in multiple ways from actions to improve patient safety, ranging from greater trust, better performance and lives saved

While the evidence base evaluating the economic impact of actions to improve patient safety is apparently under-developed in Europe, we found that, in some countries, there are both pilot and new studies beginning to investigate the social impact of the proposed action areas, such as reporting and learning systems. But, ultimately, any concrete social impacts arising from any of the three action areas will require developing future research and evaluation, particularly on the differences between and within the stakeholder groups we identified.

Nonetheless, our interview data suggests that there will be multiple benefits to patients, care providers and also healthcare systems from establishing effective reporting and learning systems. Benefits accrue to patients in the form of increased participation and empowerment (i.e. health literacy), honesty in the doctor–patient relationship, better managed expectations and lives saved. Benefits to care providers come from better culture and working environment, continuous knowledge exchange (education, awareness and skills) and accountability. Similarly, healthcare systems benefit from greater civic trust, better care provision and, consequently, avoided costs. The social impact of redress mechanisms is also significant: fair compensation undeniably benefits all injured patients; the benefit is primarily as moral compensation; fair redress mechanisms benefit health professionals through a greater sense of security (i.e. less fear) and a new blame-free culture that fosters transparency and trust; and, healthcare systems benefit from fair redress mechanisms in terms of fulfilling moral and legal obligations to citizens through greater safety vigilance and possibly cost savings. Finally, the social impact of Action Area 3 seemed overwhelmingly positive, but most directly for health professionals.

There is considerable potential to improve patient safety in Europe and all actions areas are likely to reap the potential benefits of greater knowledge for improved patient safety

Our study clearly revealed the need to know more about the effectiveness and impact of reporting and learning systems, redress mechanisms and the use and the development of knowledge and evidence at the EU level. We also found that in gaining such knowledge, particularly from an evaluation perspective, there is indeed a large potential for improvements in patient safety processes and, more critically, outcomes. Our exploratory quantitative analysis of health benefits showed there is great potential for below-average EU countries to improve to the level of above-average countries, revealing a large reduction in adverse events, associated readmissions and additional lengths-of-stay. For example, by extrapolating the additional length of stay due to adverse events found in the Spanish

national study of hospitals to the EU-27, we found that EU citizens may spend an additional 140,626 person-years in hospital as a result of adverse events, of which 50,845 person-years could have been prevented.

The expected social and economic impacts of the three Action Areas are driven by common underlying factors: culture, priority-setting and media

Our interview data revealed a number of emerging themes common to the experts' assessments of all three Action Areas. First, the majority of respondents remarked on the issue of changing culture: culture change was described as being not only a pre-condition for future action to improve patient safety, but also an integral component of patient safety action as well as being a possible policy outcome. We identified six different kinds of culture implicated in actions to improve patient safety. Second, one of the underlying factors driving the expected impacts of the different Action Areas, as described by the expert respondents, was the timing of patient safety on the political agenda in terms of priority-setting. Our analysis revealed that while patient safety is now a high priority on the political agenda of a majority of European countries, but the political nature of the issue can present barriers to assessing action impacts. Finally, the third underlying factor driving the expected impacts of the proposed Action Areas was the media: the social and economic impacts of actions will be positive if the media is a strong supporter of the proposed Action Areas (e.g. publicising mitigation strategies and other actions to improve patient safety), or the impacts will be negative if the media is an adversary to proposed actions (e.g. publicising high numbers of death and disability from adverse events).